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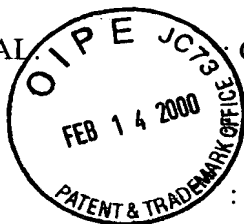
IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF:

MANFRED ASSMUS ET AL. : GROUP ART UNIT: 1712

SERIAL NO: 08/813,950

FILED: MARCH 3, 1997



: EXAMINER: SELLERS

FOR: THERMOPLASTIC COATING AND
BINDING AGENT FOR MEDICINAL
FORMS

REPLY BRIEF

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

The following is submitted in reply to the Examiner's Answer of February 1, 2000.

Noted
2/24/00
The Examiner, relying on In re Thorpe, 227 USPQ 964, states that "the patentability of a product does not depend on its method of production". It is thus his position that while, concededly, De Haan relates to a method of solvent-blending its components, nevertheless, the product obtained by such solvent-blending assertedly would be the same as one obtained by melt-mixing.

It is submitted that this is not a viable position under the facts of this case wherein it has factually been demonstrated that the claimed limitations with regard to the conditions of the preparation of the product are significant and material resulting in an unexpectedly improved product. This is also consistent with the holding in In re Marosi, 218 USPQ 289, also cited by the Examiner, recognizing that any presumption of obviousness is rebuttable. Such clearly has been done herein. Note the direct comparative evidence in the case,

particularly with regard to the European Patent, the closest prior art.

With regard to the Examiner's assertion of an alleged inconsistency in the morphology of the starting materials and product, it manifestly is in error. As so disclosed in the specification and claimed, the mixture of A and B is a non-homogenous mixture, both before and after hot-melting. However, hot-melting must be effected at a temperature of 100 to 150°C so as to obtain a homogeneous mixture when hot-melted. The defined incompatibility, i.e., non-homogeneous mixture, has the effect that in the solidified melt after hot-melting components A and B are present as separate phases, and flow improver B is not present dissolved in polymer phase A as a plasticizer. Such provides for an improved flowing capacity of the melt, without a plasticizing effect which would lead to sticky surfaces on the product. Note, in particular, page 11, lines 13-17 of the specification disclosing:

Flow improver B includes substances that can be mixed in an essentially homogeneous manner with the melt of polymer A and improve the flowability of the melt, but can be separated when the melt is cooled and solidified as its own phase.

Also, as so disclosed at page 7, line 22 to page 8, line 3:

A good flowing capacity and a melt viscosity of less than 500 Pa·sec, preferably 1 to 200 P·sec, result from the compatibility in the melt state. In this way, a rapid plasticizing, a low processing temperature, low shear forces during processing, connected with a low thermal decomposition, a complete and precise filling of mold tools and a closed, low-pore surface of the solidified melt are attained.

Manifestly, thus, no inconsistency is present in the disclosure and claims. It is due to the particular condition of hot-melting, i.e., at 100 to 150°C, recognizable by optical clarity, that unexpectedly improved results are obtained.

Subsequent to the hot-melting, however, components A and B are present as separate phases, a flow improver B is not present dissolved in polymer phase A as a plasticizer, as in

the prior art. Such provides for an improved flowing capacity of the melt, without a plasticizing effect which would lead to sticky surfaces.

With regard to Mueller, contrary to the Examiner's assertion, the presence of a hydroxyalkyl cellulose is essential and critical to its invention, it materially affecting the basic and novel characteristics of its composition. The "consisting essentially of" language of the claims thus manifestly precludes its presence, although such language permits the further presence of other conventional materials conventionally used as additives. The significance of the presence of a hydroxyalkyl cellulose in the composition of Mueller as an essential and critical component thereof palpably is evident from its disclosure and need not necessarily be additionally factually demonstrated by Applicants.

Further, it is to be pointed out that claimed flow improver B must have an average molecular weight under 20,000 d, so specifically claimed. Hydroxyalkyl celluloses, on the other hand, usually have molecular weights much greater than 20,000 d. Note Kirk-Othmer, Encyclopedia of Chemical Technology, 4th Edition, 1993, pages 548 to 549, a copy of these pages being attached.

With regard to the Declarations under 35 U.S.C. §1.132, of record, the evidence therein manifestly is not confusing, as asserted by the Examiner. They clearly factually demonstrate unexpected results for the hot-melt temperature of 100 to 150°C, as claimed. As pointed out above, the blend of A and B is a non-homogeneous mixture only when solidified, it being homogeneous when hot-melted at the claimed temperature. This is clear from both the disclosure and claim language. As such, the comparative evidence palpably establishes unobvious and unexpected results due to the claimed hot-melting temperature, specifically also as compared to the closest prior art, i.e., the European patent wherein the components are

melted at 65°C.

For reasons as set forth and urged in the Appeal Brief amplified by the above, it is again submitted that the claims define a patentable invention. Reversal of the Examiner's rejection of the claims under 35 U.S.C. §103 thus is requested.

Respectfully submitted,

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